

### REMARKS

Reconsideration of the present application in view of the above Amendments and following remarks is respectfully requested. Claims 17, 19-35, 37, 38, and 40-53 were pending. The Examiner has withdrawn claims 22-29 and 31-34. Applicants note that the Office Action Summary of Disposition of Claims includes claim 36 in the listing of currently pending claims. As indicated in the Amendment under 37 C.F.R. § 1.121 submitted November 13, 2006, claim 36 was cancelled. Applicants further note that claim 36 is not listed as withdrawn, rejected, objected to, or allowed in the Disposition of Claims and is listed as being cancelled at page 2 of the Office Action, line 2 under Response to Amendment. Therefore, Applicants assume that listing of claim 36 as pending in the Disposition of Claims is merely a typographical error.

To place the application in condition for allowance, Applicants have cancelled claims 17, 19-35, 37, 38, and 40-53 without acquiescence to any rejection and without prejudice to prosecuting the cancelled subject matter in a related divisional, continuation, or continuation-in-part application and have added new claims 54-59. Applicants submit that no new matter has been added to the application. Support for new claims 54-59 may be found, in part, in cancelled claims 45, 40, 46, 47, 45, and 38, respectively, and throughout the specification, for example, at page 7, lines 4-18; page 7, line 30 through page 8, line 5; page 8, lines 23-37; page 9, lines 23-25; page 13, lines 22-25; page 14, lines 21-32; page 15, lines 10-28; page 21, lines 15-20; page 26, lines 8-13; Figure 2 and page 3, lines 9-12. Upon entry of these Amendments, claims 54-59 will be pending and under examination.

The specification has been amended to identify trademarks in accordance with M.P.E.P. § 608.01(v) and to correct typographical errors. The specification has also been amended to change the verb tense from past to present in Example 7 (paragraph beginning at page 34, line 20). Specifically, this Example has been amended to indicate that the example outlines steps of protocols and procedures that may be performed. No new subject matter has been added by this Amendment.

### **ELECTION/RESTRICTIONS**

The Examiner objects to the application, asserting that claims 22-29 and 31-34 are directed to an invention that was not elected, with traverse, in the response dated February 27,

2004. The Examiner states that a complete reply to the Office Action dated March 8, 2007 requires cancellation of the non-elected claims or other appropriate action such as filing a petition under 37 C.F.R. § 1.144.

In view of the Amendments submitted herewith, which include cancellation of claims 22-29 and 31-34 without prejudice, Applicants submit that the objection to the application has been obviated and further submit that new claims 54-59 are directed to elected subject matter.

#### **PRIORITY**

In the Office Action dated October 14, 2005, the Examiner asserted that U.S. Provisional Application No. 60/269,840 (filing date: February 21, 2001) to which the present application properly claimed priority under 35 U.S.C. § 119(e) did not provide adequate support for then pending claims 17-21, 30, and 35-45. The Examiner examined the claims based “on the filing date of 2-21-05” [*sic*, February 21, 2002]) of the present application (*see* Office Action dated October 14, 2005 at page 2 under “Priority”). In view of the amendments submitted herewith, Applicants respectfully request reconsideration and recognition that the present application is entitled to the benefit of U.S. Provisional Application No. 60/269,840 such that the effective filing date of the present application is February 21, 2001.

#### **OBJECTION TO THE SPECIFICATION**

The Examiner objected to the specification, asserting that trademarks were not identified correctly. The Examiner requires that trademarks in the specification must be capitalized and accompanied by generic terminology.

Applicants have amended the specification to identify trademarks and to identify names used in trade, in accordance with M.P.E.P. § 608.01(v). Applicants have used best efforts to identify and properly designate trademarks and names used in trade throughout the entire application and have amended the specification accordingly (*see* pages 2-7 herein).

Applicants therefore respectfully submit that the specification meets the formality requirements and request that this objection be withdrawn.

#### **DOUBLE PATENTING**

The Examiner asserted that claims 17-21 and 30 of the present application conflict with claims 18-20, 22, and 35-38 of co-pending U.S. Application No. 10/476,614.

Applicants submit that in view of the Amendments submitted herewith, which include cancellation of claims 17, 19-21, and 30 (claim 18 was previously cancelled) and the addition of new claims 54-59, the present claims in this application do not conflict with claims 18-20, 22, and 35-38 in co-pending U.S. Application No. 10/476,614.

The Examiner also provisionally rejected claims 17 and 19-21 under 35 U.S.C. § 101, asserting that the subject matter of these claims is the same as the subject matter claimed in claims 17-21 and 30 of co-pending U.S. Application No. 10/476,614.

Applicants note that claims 17, 21, and 30 in co-pending U.S. Application No. 10/476,614 have been cancelled (see Reply and Amendment submitted January 29, 2007). Applicants further submit that in view of the Amendments submitted herewith, the subject matter recited in new claims 54-59 and the subject matter recited in claims 18-20 of co-pending application No. 10/476,614 do not conflict, and submit that the claims in each application do not claim the same structures. Accordingly, Applicants respectfully request that this rejection be withdrawn.

#### **REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH (WRITTEN DESCRIPTION)**

(1) The Examiner rejected claims 17, 19-21, 35, 37-38, and 40-53 under 35 U.S.C. § 112, first paragraph, asserting that the claims are directed to subject matter that is not adequately described in the specification. The Examiner asserts that the specification does not support that the claimed polypeptide fragments or analogs bind to “BVH-P7 of *S. pyogenes*.”

Applicants respectfully traverse this rejection and submit that, as disclosed in the specification and recited in present claims 54-59, the application reasonably conveys to a person skilled in the art that Applicants possessed the claimed invention at the time of filing. As an initial matter and as noted above, Applicants have cancelled claims 17, 19-21, 35, 37-38 without acquiescence or prejudice. The present claims are directed, in pertinent part, to an isolated polypeptide comprising the amino acid sequence set forth in SEQ ID NO:2, and variants thereof that comprise an amino acid sequence at least 95% identical to the full-length amino acid

sequence set forth in SEQ ID NO:2, wherein the polypeptides are capable of eliciting an immune response to *Streptococcus pyogenes* and are capable of eliciting an antibody that specifically binds to a BVH-P7 polypeptide that consists of the amino acid sequence set forth in SEQ ID NO:2; to pharmaceutical compositions comprising such polypeptides; and to polypeptide fragments consisting of at least ten contiguous amino acids of a polypeptide consisting of the amino acid sequence set forth in SEQ ID NO:2 (*see* specification, for example, at page 7, lines 4-18; page 7, line 30 through page 8, line 12; page 8, lines 23-37; page 9, lines 24-25; and Examples therein).

Applicants submit that the specification sufficiently describes the claimed embodiments recited in claims 54-59, and, thus, the application complies with the written description requirements under 35 U.S.C. § 112, first paragraph.

(2) The Examiner also rejected claims 17, 19-21, 35, 37-38, and 40-53 under 35 U.S.C. § 112, first paragraph, asserting that the claims are directed to subject matter that is not adequately described in the specification. The Examiner asserts that the specification does not describe polypeptides at least 90%, 80%, or 70% identical to the amino acid sequence of SEQ ID NO:2.

Even though Applicants respectfully disagree with the Examiner, without acquiescence or prejudice, claims 17, 19-21, 35, 37-38, and 40-53 have been cancelled. Applicants submit, and the Examiner agrees (*see* Action, page 5), that the present specification adequately describes a BVH-P7 polypeptide comprising the amino acid sequence set forth in SEQ ID NO:2 and variants thereof that comprise an amino acid sequence at least 95% identical to SEQ ID NO:2 and that are capable of eliciting an immune response to *Streptococcus pyogenes* and that are capable of eliciting an antibody that specifically binds to a BVH-P7 polypeptide that consists of the amino acid sequence set forth in SEQ ID NO:2 (*see* new claim 54) (*see* specification, for example, at page 7, lines 4-18; page 7, line 30 through page 8, line 12; page 8, lines 23-37; page 9, lines 24-25; and Examples therein).

Applicants submit that the present specification reasonably conveys to a person skilled in the art that Applicants possessed the presently claimed embodiments at the time the

application was filed and that the application satisfies the written description requirements under 35 U.S.C. § 112, first paragraph.

**REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH (ENABLEMENT)**

The Examiner rejected claims 17, 19-21, 35, 37-38, and 40-53 under 35 U.S.C. § 112, first paragraph, asserting that certain claimed subject matter is not enabled by the specification. The Examiner asserts that the disclosure in the specification is not commensurate with the scope of the claims.

Applicants respectfully submit that this rejection is rendered moot in view of the Amendments submitted herewith, which include cancellation of claims 17, 19-21, 35, 37-38, and 40-53 without acquiescence or prejudice. Applicants submit, and the Examiner agrees (*see* Action, page 5), that the specification teaches a person skilled in the art how to make and use, readily and without undue experimentation, a polypeptide comprising the amino acid sequence set forth in SEQ ID NO:2, and variants thereof that comprise an amino acid sequence at least 95% identical to the full-length amino acid sequence set forth in SEQ ID NO:2, wherein the polypeptides are capable of eliciting an immune response to *S. pyogenes* and are capable of eliciting an antibody that specifically binds to a BVH-P7 polypeptide that consists of the amino acid sequence set forth in SEQ ID NO:2; to pharmaceutical compositions comprising such polypeptides; and to polypeptide fragments consisting of at least ten contiguous amino acids of a polypeptide consisting of the amino acid sequence set forth in SEQ ID NO:2.

Applicants submit that given the disclosure in the application (including numerous working examples), the state of the art, and the skill level of a person skilled in the art, the polypeptides and related compositions as recited in present claims 54-59 are enabled by the specification. Thus, the scope of the present claims is commensurate with the disclosure in the specification, satisfying the requirements for enablement under 35 U.S.C. § 112, first paragraph.

**REJECTIONS UNDER 35 U.S.C. § 102**

(1) The Examiner rejected claims 17, 19, 35, and 36 under 35 U.S.C. § 102(b), asserting that the claimed subject matter is anticipated by Dixon et al. (PIR\_79 Database Accession No. T51594, August 18, 2000). The Examiner asserts that Dixon et al. teach a

polypeptide that has nine contiguous amino that are identical to nine contiguous amino acids of SEQ ID NO:2 disclosed in the present application.

Applicants submit that this rejection is rendered moot in view of the Amendments submitted herewith that include cancellation of claims 17, 19, 35, and 36 without acquiescence or prejudice. Moreover, Dixon et al., fail to teach or suggest the claimed subject matter as recited in present claims 54-59. Particularly, the cited reference fails to teach or suggest an isolated polypeptide fragment consisting of at least ten contiguous amino acids of the polypeptide comprising the amino acid sequence set forth in SEQ ID NO:2 (*see* present claim 59). Applicants also submit that the instant claims are supported by the provisional application to which the present application claims the benefit of priority; therefore, the present application has an effective filing date of February 21, 2001, and Dixon et al. is not prior art under 35 U.S.C. § 102(b).

(2) The Examiner rejected claims 17, 19, 35, and 36 under 35 U.S.C. § 102(b), asserting that the claimed subject matter is anticipated by McDonald et al., (PIR\_79 Database Accession No. JE0176, July 3, 1998). The Examiner asserts that McDonald et al. teach a polypeptide that has nine contiguous amino that are identical to nine contiguous amino acids of SEQ ID NO:2 disclosed in the present application.

Applicants submit that this rejection is rendered moot in view of the Amendments submitted herewith that include cancellation of claims 17, 19, 35, and 36 without acquiescence or prejudice. Moreover, McDonald et al., fail to teach or suggest the claimed subject matter as recited in present claims 54-59. Particularly, the cited reference fails to teach or suggest an isolated polypeptide fragment consisting of at least ten contiguous amino acids of the polypeptide comprising the amino acid sequence set forth in SEQ ID NO:2 (*see* present claim 59).

(3) The Examiner rejected claims 17, 19, and 35-38, and 40-45 under 35 U.S.C. § 102(a), asserting that the claimed subject matter is anticipated by Ferretti et al. (*Proc. Natl. Acad. Sci. USA* 98:658-63 (April 10, 2001)). The Examiner asserts that the claims “recite open language and not “consisting of,” therefore the polypeptides of the prior art comprise the claimed fragments.” (See Action, at page 8, last three lines.)

Applicants submit that this rejection is rendered moot in view of the Amendments submitted herewith that include cancellation of claims 17, 19, and 35-38, and 40-45 without acquiescence or prejudice. Moreover, Ferretti et al. fail to teach or suggest the claimed subject matter as recited in present claims 54-59. Particularly, the cited reference fails to teach or suggest an isolated polypeptide fragment consisting of at least ten contiguous amino acids of the polypeptide comprising the amino acid sequence set forth in SEQ ID NO:2 (*see* present claim 59). Applicants also submit that the instant claims are supported by the provisional application to which the present application claims the benefit of priority; therefore, the present application has an effective filing date of February 21, 2001, and the cited document is not prior art.

(4) The Examiner rejected claims 17, 19, 20, 21, 30, and 35-38, 41, 42, and 43 under 35 U.S.C. § 102(a), asserting that the claimed subject matter is anticipated by LePage et al. (International Patent Application Publication No. WO 01/32882, published May 19, 2001). The Examiner asserts that the claims “recite open language and not “consisting of,” therefore the polypeptides of the prior art comprise the claimed fragments.”

Applicants submit that this rejection is rendered moot in view of the Amendments submitted herewith that include cancellation of claims 17, 19, 20, 21, 30, and 35-38, 41, 42, and 43 without acquiescence or prejudice. Moreover, LePage et al. fail to teach or suggest the claimed subject matter as recited in present claims 54-59. Particularly, the cited reference fails to teach or suggest an isolated polypeptide fragment consisting of at least ten contiguous amino acids of the polypeptide comprising the amino acid sequence set forth in SEQ ID NO:2 (*see* present claim 59). Applicants also submit that the instant claims are supported by the provisional application to which the present application claims the benefit of priority; therefore, the present application has an effective filing date of February 21, 2001, and the cited document is not prior art.

Accordingly, present claims 54-59 meet the requirements for novelty under 35 U.S.C. § 102. Applicants respectfully submit that these claims meet the requirements for patentability and are allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

Application No. 10/078,531  
Reply to Office Action dated March 8, 2007

The Director is authorized to charge any additional fees due by way of this  
Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Respectfully submitted,  
SEED Intellectual Property Law Group PLLC

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